with the operation are under positive control as defined in the applicable SOP and that the operation complies with the criteria of this regulation and DA Pam 385–69.

§626.9 Inspections.

(a) Biosafety laboratories require periodic (at least quarterly for BL–1 and BL–2 and monthly for BL–3 and BL–4 laboratories), inspections by safety and health professionals. Safety officials will document the inspections, assure that deviations from safe practices are recorded, and that recommended corrective actions are taken. If deviations are life threatening, this area will be restricted until corrective actions are accomplished. New RDTE efforts involving etiologic agents will be evaluated and inspected prior to start-up to assure equipment, facilities, employee training, and procedures are in place and adequate for the introduction of BDP material. Safety officials will maintain such records for 3 years and will review the records at least annually for trends requiring corrective actions.

(b) Supervisors shall inspect work areas frequently (at least weekly) and take corrective actions promptly.

§626.10 Transportation of BDP etiologic agents.

(a) Etiologic agents utilized in the BDP shall be packed, labeled, marked, prepared for shipment, and shipped in accordance with applicable Federal, State, and local laws and regulations, to include 42 CFR part 72, ''Interstate Shipment of Etiologic Agents,'' 49 CFR parts 172 and 173 (Department of Transportation), 9 CFR part 122 (USDA Restricted Animal Pathogens), and DA Pam 385–69.

(b) Etiologic agents shipped to support the BDP will use secondary shipping containers which are sealed with a crimped lid (see app D, DA Pam 385–69).

(c) BDP organizations and contractors who provide etiologic agents will ship all etiologic agents by private carrier. The United States Postal Service will not be used to transport etiologic agents required for the BDP.

(d) In addition to the above requirements, shipments of BL–4 etiologic agents will be hand carried by Government courier or under the immediate supervision of a responsible party. This individual must be knowledgeable about the potential hazards of the materials and be able to monitor all aspects of the shipment to ensure that required transfers have been completed and documented and final receipt has been accomplished and acknowledged.

(e) Audit trails of all BDP etiologic agent shipments and receipts of such agents shall be established and maintained for at least 3 years. Such audit trails shall identify date of shipment, carrier, addresses of the shipper and recipient, and agent(s) shipped and received.

§626.11 General construction plans.

General construction plans for BDP facilities, as well as for changes in use of facilities, will be submitted through the chain of command to HQDA, Army Safety Office, DACS–SF, WASH DC 20310–0200 for safety review and approval. Plans shall be forwarded for new construction or major modifications of facilities used in the BDP. The facility system safety requirements of AR 385–16 and AR 415–15 shall be followed. Simultaneously, RDTE requirements that necessitate such renovation, modification, or construction shall be submitted through the chain of command to HQDA, OASA(RDA), SARD–ZT, WASH DC 20310–0103 for review and approval.

§626.12 Maximum credible event (MCE).

(a) Because of the complexity of the RDTE conducted in the BDP, the range of potential consequences that could be associated with a mishap must be considered. MCE is a risk analysis technique which provides a useful tool for estimating the effectiveness of existing safeguards. The potential for events must be carefully analyzed to determine the MCE that could occur and cause a mishap. All hazard analysis and general construction plans mentioned in §626.11 will include a consideration of an MCE.

(b) The term MCE, as used herein, is analogous to a realistic worst-case analysis. The best available credible information will be applied to estimate

the results of various MCEs. Those assumptions that yield the potential for more severe consequences, as opposed to assumptions that operational and safety controls will always perform as designed, will be used. The rule of reason will be applied to confine the MCE to realistic or believable occurrences.

(c) When considering an MCE, consider the redundancy of safety systems engineered into the facilities and the equipment used, depending on containment level required to make them as fail-safe as practical. The MCE for containment laboratories must be considered in terms of physical containment for both toxins and biological organisms. Therefore, both toxin and biological MCEs will be considered.

(d) Because aerosols of etiologic agents represent the most significant potential hazard for exposure of workers or the environment, a hazard analysis (to include MCE) of proposed BDP RDTE activities will be performed to determine the procedures, engineering controls, and facility design required to mitigate potential significant hazards.

§ 626.13 Controls.

(a) Personnel who are not needed to operate a BDP laboratory, will not be allowed to enter potentially hazardous areas.

(b) Written procedures to control access and ensure that personnel can be evacuated or protected from exposure may be used in place of absolute personnel exclusion.

§ 626.14 Waivers and exemptions.

(a) The goal of the biological defense safety program is strict adherence to safety standards and the elimination of all waivers and exemptions.

(b) Waiver authority. (1) The Chief of Staff, Army (CSA) is the controlling authority for granting waivers of biological defense safety standards. This authority is redelegated by this regulation to commanders of MACOMs and the commander of the USAMRDC.

(2) Waiver authority will not be subdelegated.

(3) Commanders with waiver authority will—

(i) Ensure the existence of necessary and compelling reasons before granting waivers.

(ii) Grant waivers to standards for installations and activities within their areas of authority.

(c) Waiver requests: (1) Commanders of installations and activities will submit a request for waiver when compliance with these standards cannot be achieved. When such waivers affect on other commands, initiating activities will coordinate requests with those commands.

(2) Requests for waivers will contain the following information:

(i) Description of conditions. State the mission requirements and compelling reasons which make the waiver essential and the impact if not approved, and describe all affected sites or facilities and the quantity and type of BDP required.

(ii) The safety regulations, including specific safety requirements or conditions cited by paragraph, from which the waiver is requested, and the reasons for the waiver.

(iii) Specific time period for which the waiver is requested.

(iv) A hazard analysis which identifies actual and potential hazards which can result from the waived requirements or conditions.

(v) A risk assessment that provides information on the risk being assumed because of the waiver. The assessment will include those safety precautions and compensatory measures in force during the waiver period.

(vi) A waiver abatement plan to include milestones, resources, and actions planned to eliminate the need for the waiver.

(3) Requests for waivers will be forwarded through command channels to the MACOM or CG, USAMRDC, as appropriate, for approval. MACOM or USAMRDC safety officials will forward a copy of approved waivers to HQDA, DACS–SF, WASH DC 20310–0200. Copies of all waivers will be maintained at the installation and MACOM or USAMRDC Safety Offices for up to 3 years after the waiver is terminated.

(4) Time limitations: (i) Waivers are normally limited to 1 year or less, and will be considered rescinded after 1 year, unless reviewed. The activity or